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RECEIVED

APR 13 2007

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March 4, 2007

Re: Application Number 10/687,281  
Filing Date: 10/16/2003  
Inventor: Naomi L. Nakao  
Attorney Docket No: G30-014  
Confirmation Number 8977  
Examiner: Ahmed, Aamer S

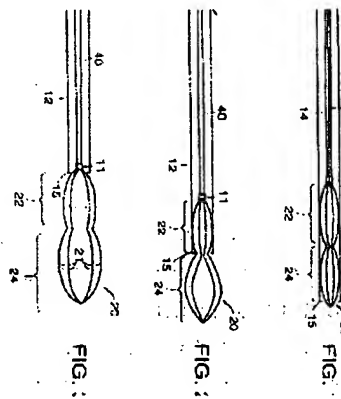
### Affidavit

I, George Triadafilopoulos, being duly sworn on oath, depose and say as follows:

1. I am a Board-certified gastroenterologist practicing gastrointestinal endoscopy 70% of the time over the past 20 years. My curriculum vitae is attached.
2. I perform colonoscopy and polypectomy on a daily basis with a cumulative experience of more than 15,000 cases.
3. I make this Declaration in support of the concurrently filed Amendment in the above-identified patent application.
4. I have reviewed the prior art references to Bates patents number 6,348,056 and 5,788,710 and the claims of both patents. I have examined a prototype that conforms to the claims and descriptions in Application Number 10/687,281 particularly including the bends at the distal ends of the loop tending to square off the loop at that end, and the ovoid configuration of the fully deployed snare despite the two middle dents. I am well familiar with both of the Bates devices, and with the Nakao Device of the above-identified patent application.
5. I find the Nakao multi-sized snare instrument to be entirely novel and extremely effective. This instrument is dearly needed, especially in the cost conscious medical environment of today. At present, small snares are used to transect small polyps, while large snares are used to transect large polyps. The Nakao Snare device enables a hospital or surgery center to purchase one type of snare only because the Nakao Snare may be

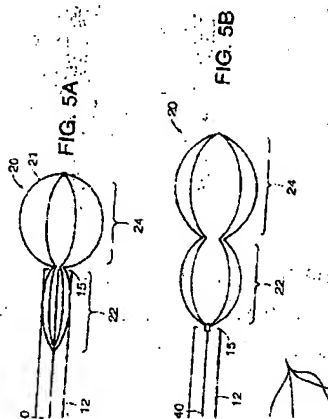
used for large as well as small polyps. This cuts down on hospital inventory and saves expenditure to the hospital and thus to the patient.

When comparing the Nakao multi-sized snare to the Bates retrieval basket, I have no doubt that the Nakao Snare is a novel invention that is an important addition to the gastroenterologist's armamentarium. Beyond the obvious fact that the Bates retrieval basket is not used to transect polyps while the Nakao device is, it is the difference in the loop configuration that makes the Nakao Snare the valuable device that it is. Here is how the two loop configurations differ: When the Bates stone retrieval basket of the '056 patent is partially retracted, the cross sectional opening span of the basket is very small. If it were to be used as a cautery snare, the endoscopist would not be capable of passing it over and snaring a round, soft polypoid lesion.



In contrast, while the Nakao multi-sized snare is capable of snaring a large, ovoid, soft polyp while in the open position, it forms a smaller, nicely ovoid loop when partially retracted due to the combination of a distal squaring off of the device and the two middle dents.

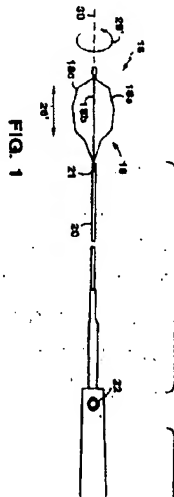
As examiner Ahmed correctly observes in the most recent office action, Bates does achieve a rounded partially retracted loop configuration in his retrieval basket as seen in the figure below (item 24 FIG 5B):



The reason that the above Bates loop design would never work in a polypectomy snare is the following: When this loop configuration is fully opened one would not be able to fit it around a large, soft polyp. In order for loop 24 to open in the above ovoid configuration during partial retraction, the indentation between loops 22 and 24 must be so severe that it would never fit over a large, soft tissue mass. If such a snare were to be passed over a large polyp, it would surely scratch or otherwise injure the lesion. But what is more likely to occur is, the endoscopist would not be capable of passing such a snare over the polyp at all. There simply would not be enough room to fit the polyp into this "double 3 configuration". Furthermore, the endoscopist operates within a confined space inside the colon lumen, where passing even a regular snare over a large polyp is not a simple maneuver. The "double 3 Bates configuration" would be virtually useless.

The reason that the Nakao snare invention is entirely novel over the Bates reference is that while there are two notches in the Nakao Snare, the notches don't change the functional configuration of the cautery snare: the state of the art cautery snare is oval shaped, with a transverse distance large enough to pass over the polyp that is about to be transected. The Nakao Snare, despite its two middle notches, maintains the general shape and functionality of a state of the art polypectomy snare. Thus, despite the two notches, when completely open, it may be easily passed over a large polyp. When the Nakao Snare is partially retracted into the catheter, the distal loop retains its ovoid shape because of the distal squaring off. The notches alone would not do it. It is this novel design combination wherein (a) the two middle dents are configured in such a fashion that, when completely open the snare functions as a regular snare would, while (b) squaring off the distal end enables the formation of a perfectly functional ovoid smaller snare.

Regarding the '710 patent, the device is illustrated below:



Snares with multiple bends along their loop are quite commonplace in today's market. Companies such as US Endoscopy Group (USEG), Boston Scientific, and Olympus sell such snares. Yet, these bends are not 90 degree bends as in the Nakao Snare design, but 120 degrees or greater. Therefore, when retracted into the catheter, the distal aspect of these snares would close upon retraction, just as a regular ovoid snare

would. The novelty of the Nakao Snare, which has been proven to work during polypectomy performed on variously sized polyps, is the clever combination of the inward dents while still maintaining the oval snare configuration, along with the distal squaring off enabling the formation of a small oval loop. It is only through this design that we could have an instrument for snaring and transecting large as well as small polyps with equal facility.

6. I have reviewed the Nakao and Bates patents relied on by Examiner Ahmed. I do not see how one of ordinary skill in this art could have derived the snare of Dr. Nakao's application from the prior art relied on by Examiner Ahmed.

Sincerely

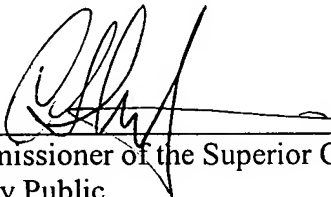
*George Triadafilopoulos*

George Triadafilopoulos, MD

NOTORIZATION

STATE OF CONNECTICUT        }  
  } ss.: Bridgeport  
COUNTY OF FAIRFIELD        }

Subscribed and sworn to this 13th day of April, 2007, by GEORGE  
TRIADAFILOPOULOS, MD, to me personally known, or satisfactorily proven to be the  
person whose name is subscribed to the above Affidavit.

  
\_\_\_\_\_  
Commissioner of the Superior Court  
Notary Public

(SEAL)

## **CURRICULUM VITAE**

**George Triadafilopoulos, MD, DSc, FACP, FACG, FAGA, FASGE**

### **PERSONAL DATA**

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### **EDUCATION**

1973 High school Diploma with honors, 2nd Gymnasium, Patras, Greece  
1979 Doctor of Medicine, *Summa Cum Laude*, Aristotelian University Medical School,  
Thessaloniki, Greece

### **GRADUATE MEDICAL EDUCATION**

1980-1981 Intern in Internal Medicine, Wayne State University Affiliated Hospitals, Detroit, Michigan  
1981-1982 Resident in Internal Medicine, Wayne State University Affiliated Hospitals, Detroit, Michigan  
1982-1983 Senior Resident in Internal Medicine, Sinai Hospital of Detroit, Detroit, Michigan  
1983-1985 Clinical and Research Fellow in Gastroenterology, Boston University Medical Center, Boston, Massachusetts (Combined Program: University Hospital-Boston City Hospital)

**PROFESSIONAL LICENCES**

1980 Medical License, Hellenic Ministry of Health, Greece  
 1980 Medical License, Michigan Board of Medicine  
 1982 Medical License, Commonwealth of Massachusetts  
 1989 Medical License, California State Board of Medical Quality Assurance  
 (A45948, expires 8/31/07)

**DIPLOMAS**

1983 Diploma, Specialty of Internal Medicine, Hellenic Ministry of Health, Greece  
 1983 Diploma, Specialty of Internal Medicine, American Board of Internal Medicine  
 1986 Diploma, Specialty of Gastroenterology, Hellenic Ministry of Health, Greece  
 1986 Diploma, Specialty of Gastroenterology, American Board of Internal Medicine

**AWARDS**

1979 M.D., *Summa Cum Laude*, Aristotelian University Medical School, Thessaloniki, Greece  
 1985 American Gastroenterological Association Research Training Award  
 1986 D.Sc. with Honors, Patras Medical School, Patras, Greece  
 1989 Dean's Research Award, University of California, Davis  
 1993 American Federation for Aging Research - John A. Hartford Foundation Faculty Award  
 1997 Dean's Research Award, Stanford University  
 1998 M.D., *Doctor Honoris Causa*, Universitatea din Oradea, Romania

**ACADEMIC and PROFESSIONAL POSITIONS**

1979-1980 Research Associate, Aristotelian University Medical School, Thessaloniki, Greece  
 1983-1985 Associate in Medicine, Boston University Medical School, Boston, MA  
 1985-1986 Instructor in Medicine, Boston University Medical School, Boston, MA  
 1985-1988 Assistant Physician, Evans Memorial Department for Clinical Research, University Hospital, Boston, MA  
 1985-1988 Director, Gastrointestinal Motility Laboratory, University Hospital, Boston, MA  
 1985-1988 Assistant Visiting Physician, Department of Medicine, Boston City Hospital, Boston, MA  
 1986-1988 Assistant Professor of Medicine, Boston University Medical School, Boston, MA  
 1988-1991 Assistant Professor of Medicine, University of California-Davis School of Medicine, Davis, CA  
 1991-1992 Associate Clinical Professor of Medicine, University of California-Davis School of Medicine, Davis, CA  
 1988-1992 Chief, Section of Gastroenterology and Director, Gastroenterology Fellowship Program, University of California-Davis East Bay Program at Martinez Veterans Administration Hospital and St. Mary's Hospital, San Francisco, CA.  
 1992-2004 Chief, Section of Gastroenterology, Palo Alto Veterans Affairs Health Care System, Palo Alto, CA.  
 1992- Consultant Gastroenterologist, Stanford University Hospital, Stanford, CA  
 1992-98 Associate Professor of Medicine, Stanford University School of Medicine, Stanford, CA  
 1998-2004 Professor of Medicine, Stanford University School of Medicine, Stanford, CA  
 2004- Consultant Gastroenterologist, Section of Gastroenterology, Palo Alto Veterans Affairs Health Care System, Palo Alto, CA  
 2004- Consultant Gastroenterologist, El Camino Hospital, Mountain View, CA

2004- Clinical Professor of Medicine, Division of Gastroenterology and Hepatology,  
Stanford University School of Medicine, Stanford, CA

## MEMBERSHIPS

American Association for the Advancement of Science; Member  
American Association for the Study of Liver Disease; Member  
American College of Gastroenterology; Fellow  
American College of Physicians; Fellow  
American Federation for Clinical Research; Member  
American Gastroenterological Association; Fellow  
American Society for Gastrointestinal Endoscopy; Fellow  
Crohn's and Colitis Foundation of America; Member  
Gastroenterology Research Group; Member  
Northern California Society for Clinical Gastroenterology; Member  
Western Society for Clinical Investigation; Member  
The International Society for Diseases of the Esophagus; Member  
American Motility Society, Member

## OTHER PROFESSIONAL/CIVIC ACTIVITIES

1986-88 Scientific Advisory Committee Member; National Foundation for Ileitis and  
Colitis, Massachusetts Chapter  
1987- Reviewer; American Journal of Gastroenterology  
1987-92 Consultant Gastroenterologist; YGEIA Diagnostic and Therapeutic Center,  
Athens, Greece.  
1988-92 Chairman, Nutrition Committee, Martinez Veterans Administration Hospital,  
Martinez, CA  
1989- Reviewer; New England Journal of Medicine  
1989-92 Consultant Gastroenterologist; Contra Costa County Hospital, Martinez, CA  
1989-92 Preceptor, MPH Program in Nutrition, University of California at Berkeley,  
Berkeley, CA  
1990-92 Physician-in-Chief, Gastroenterology Unit and Consultant Gastroenterologist; St.  
Mary's Hospital and Medical Center, San Francisco, CA  
1990-2000 Reviewer; Digestive Diseases and Sciences  
1990-92 Medical Director, Weight Loss Program, St. Mary's Hospital and Medical Center,  
San Francisco, CA  
1990-92 Preceptor, College of Osteopathic Medicine of the Pacific, Pomona, CA  
1991-92 Consultant Gastroenterologist; John Muir Hospital and Medical Center, Walnut  
Creek, CA  
1992- Staff Gastroenterologist, Stanford University Hospital, Stanford, CA  
1993- Reviewer; Archives of Surgery  
1993- Reviewer; Gastroenterology  
1993 AGA Visiting Scholar, Gastrointestinal Motility Program, Mayo Clinic and  
Medical School, Rochester, MN  
1994-1997 Member, Training and Education Committee, American Gastroenterological  
Association  
1995- Reviewer; Gastrointestinal Endoscopy  
1996 Guest Editor, Annual Review of Medicine, Volume 49 (1998)  
1996-2000 Reviewer; Western Journal of Medicine  
1997-2000 Reviewer; Annals of Otology, Rhinology and Laryngology  
1997-2000 Reviewer; Digestive Diseases  
1997-2000 Reviewer; Accreditation Committee for Graduate Medical Education (ACGME)  
1999- Reviewer, *Gut*  
2000- Member, Reviewer's Board, Current Opinion in Clinical Experimental Research



|           |  |
|-----------|--|
| 2000-     | Member, Reviewer's Board, Current Opinion in European Medicine                                     |
| 2000-     | Reviewer; Digestive and Liver Disease  |
| 2001-2004 | Member, International Liaison Committee, American Gastroenterological Association.                 |
| 2001-2004 | Member, Editorial Board, <i>Gut</i> .  |
| 2001-     | Member, Editorial Board, Digestive and Liver Disease   |
| 2001-     | Permanent Member, Scientific Committee, Section of Gastroenterology, OESO.                         |
| 2002-     | Reviewer; Cancer Detection and Prevention  |
| 2002-     | Reviewer; Journal of Applied Physiology  |
| 2003-2004 | Co-Chair, REDUCE campaign, American Gastroenterological Association                                |
| 2004      | Member; In-service examination committee, American Gastroenterological Association                 |
| 2004      | Member, Editorial Board, World Journal of Gastroenterology   |
| 2004-     | Member Publications Committee, American Society for Gastrointestinal Endoscopy                     |
| 2004-     | Editor-in-Chief, <i>Gastrointestinal Endoscopy</i>   |
| 2004-     | Reviewer; Nature (Clinical Practice) Gastroenterology and Hepatology                               |
| 2005-     | Member, Editorial Board, Diseases of the Esophagus   |
| 2005-     | Member, IBD-transition of care committee, Children's Digestive Health and Nutrition Fund           |
| 2005-     | Gastroenterology Training Examination (GTE) Subcommittee; American Gastroenterological Association |
| 2005-     | National Editor, Hepato-Gastroenterology   |
| 2006-     | Governor for North America, International Society for Diseases of the Esophagus (ISDE)             |
| 2006-     | Member, Board of Scientific Direction, OESO.   |

## PUBLICATIONS

1. Pothoulakis C, **Triadafilopoulos G**, LaMont JT: Diagnosis and treatment of antibiotic associated colitis. *Comprehensive Therapy II*: 68-73, 1985
2. Pothoulakis C, **Triadafilopoulos G**, Clark M, Franzblau C, LaMont JT: *Clostridium Difficile* cytotoxin inhibits protein synthesis in fibroblasts and intestinal mucosa. *Gastroenterology* 91: 1147-53, 1986
3. **Triadafilopoulos G**, Pothoulakis C, O'Brien M, LaMont JT: Differential effects of *Clostridium Difficile* toxins A and B on rabbit ileum. *Gastroenterology* 93: 273-79, 1987
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5. Graham DY, Agrawal NM, Roth SH, and the Nationwide Study Group. Prevention of NSAID-induced gastric ulcer with misoprostol: Multicentre, double-blind, placebo-controlled trial. *Lancet ii*: 1277-1280, 1988.
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14. **Triadafilopoulos G**. Prevention of NSAID-induced gastric ulcers in the elderly. *Advances in Therapy* 7: 276-282, 1990.
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26. Castillo T, Koop DR, Kamimura S, **Triadafilopoulos G**, and Tsukamoto H. Role of cytochrome P450 2E1 in ethanol-, carbon tetrachloride- and iron-dependent microsomal lipid peroxidation. *Hepatology* 16: 992-996, 1992.
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42. **Triadafilopoulos G**. Commentary on "Somatostatin did not increase survival or decreased blood transfusions in bleeding esophageal varices". *ACP J. Club* 124; 1:12, 1996.
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47. Kumble S, Omary MB, Cartwright C, and **Triadafilopoulos G**. *Src* activation in malignant and premalignant lesions of Barrett's esophagus. *Gastroenterology* 112: 348-356, 1997.
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52. **Triadafilopoulos G**. Primary esophageal motility disorders: Incisive decisions (Editorial) *The Western Journal of Medicine* 166: 289-290, 1997
53. Kim MJ, Michener R, and **Triadafilopoulos G**. Serum <sup>13</sup>C-bicarbonate assay for the diagnosis of gastric *Helicobacter pylori* infection and response to treatment. *Gastroenterology* 113: 31-37, 1997
54. **Triadafilopoulos G**. Appendicitis or right-sided diverticulitis? Image of the Month. *Gastroenterology* 113: 1062, 1997.
55. **Triadafilopoulos G**, and Sharma R. Features of symptomatic gastroesophageal reflux disease in elderly patients. *Am. J. Gastroenterol.* 92: 2007-2011, 1997.

56. Fitzgerald RC and **Triadafilopoulos G**. Recent developments in the molecular characterization of Barrett's esophagus. *Digestive Diseases* 16: 63-80, 1998.
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60. Fitzgerald RC, Omary MB and **Triadafilopoulos G**. Acid modulation of sodium-hydrogen exchange activity in Barrett's esophagus and its effect on cell proliferation. *Am. J. Physiol.* 275: G47-55, 1998.
61. **Triadafilopoulos G**, Finlayson MA and Grellet C. Bowel dysfunction in postmenopausal women. *Women & Health* 27: 55-66, 1998
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63. Singh G, and **Triadafilopoulos G**. Epidemiology of NSAID-induced GI complications. *J. Rheumatol.* 26 (Supplement 56): 18-24, 1999.
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## ABSTRACTS and PRESENTATIONS

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